DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

August 26, 1999

WARNING LETTER NYK 1999-66

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stanley W. Cipkowski, President and CEO
American Bio Medica Corporation
300 Fairview Avenue
Hudson, New York 12534

Dear Mr. Cipkowski:

U. S. Food and Drug Administration (FDA) Investigator Nancy A. Saxenian conducted an inspection of your facility at 300 Fairview Avenue, Hudson, New York on February 3 through 16 and March 3, 1999. The inspection revealed your 5 Panel Rapid Drug Screen manufactured at your facility is adulterated within the meaning of Section 501(f)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act) because your firm substantially increased the cut-off values used to interpret the test results without having an approved application for premarket approval in effect under Section 515(a) or an approved application for an investigational device exemption under Section 520(g) of the Act. These approvals are required unless you have submitted a premarket notification submission that shows that the modified 5 Panel Rapid Drug Screen is substantially equivalent to other devices that are legally marketed and you have been notified by FDA that you may market the modified 5 Panel Rapid Drug Screen. The cut-off values identified in the 510(k) differ significantly from those identified in the package insert currently in use.

In addition, the inspection revealed the 5 Panel Rapid Drug Screen is in further violation as follows:

- The use of the increased cut-off concentrations causes this device to be misbranded within the meaning of Section 502(o) because your firm changed the device substantially without submitting a notice or other information to FDA regarding this modification prior to introducing the device into interstate commerce as required by Section 510(k) and Title 21, Code of Federal Regulations (21 CFR) 807.81(a)(3);

- The device is misbranded within the meaning of Section 502(c) because the expiration date appearing on the foil pouches is not in such terms likely to be read and understood by the ordinary individual under customary conditions of use. There is a lack of contrast between the embossed characters and the white foil of the pouch. Also, the embossed characters of the expiration date are combined into one string with the embossed characters of the sequential batch number and the format is not one which would be readily interpreted to mean the kit expires in a particular month and year;

- The device is misbranded within the meaning of Section 502(f)(1), because the labeling fails to bear adequate directions for use as required by 21 CFR Section 809.10(a)(5) Labeling for In Vitro Diagnostic Products. For example, the labeled expiration dates were not based upon reliable, meaningful, and specific test methods.

The above identification of violations is not intended to be an all-inclusive list of deficiencies regarding your product. It is your responsibility to ensure all devices distributed by your firm meet the requirements of the Act, and the regulations promulgated thereunder. Federal agencies are advised of all warning letters regarding devices so that they may take this information into account when considering the award of contracts.

We are also interested in a description of any changes or modifications, other than labeling changes, that have been made to the 5 Panel Rapid Drug Screen since the premarket notification was submitted on November 26, 1996, and comment on whether these changes affect the cut-off concentrations.

We received your letters dated February 19, May 27, June 24, 1999, and August 16, 1999 providing responses to the observations listed on the FDA 483 and to the issues raised by James M. Kewley, Compliance Officer. Our assessment finds your responses are not adequate. We believe a meeting with representatives of your firm is indicated, in addition to any written response you with to make. The meeting should be scheduled as soon as possible, but within fifteen (15) working days of receipt of this letter. Please contact Lisa M. Utz, Compliance Officer, at (716) 551-4461 ext. 3165 for scheduling purposes.

Sincerely,

Brenda J. Holman
District Director